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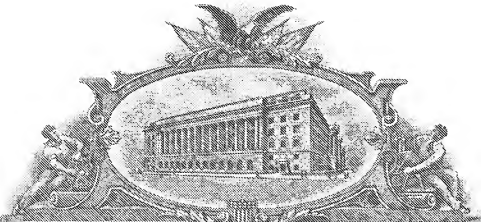

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PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53(b)(2).

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TITLE OF THE INVENTION (500 characters max)

MULTIFUNCTION INFANT MONITORING SYSTEM

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[☒] Applicant Claims Small Entity Status

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☒ No
☐ Yes, the name of the Government Agency and the Government Contract Number are:

Respectfully submitted,

Mark E. Books Date: 1/29/04

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SPECIFICATION

To All Whom It May Concern:

Be It Known That I, **Elvir Causevic** citizen of the United States, resident of the City of Ellisville, State of Missouri, whose full post office address is 16315 Autumn View Terrace, Ellisville, Missouri 63011 have invented certain new and useful improvements in a

MULTIFUNCTION INFANT MONITORING SYSTEM

Express Mail No.: EV 383194217 US

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] Not Applicable.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

[0002] Not Applicable.

BACKGROUND OF THE INVENTION

[0003] The present invention is related generally to medical screening devices, and in particular, to a medical screening device configured to measure and monitor combinations of blood chemistry, breath gasses, and bioelectrical signals such as evoked auditory signals, EEG signals, and EKG signals associated with infant auditory testing to facilitate detection of abnormal medical conditions in human infants.

[0004] Hyperbilirubinemia is a serious condition affecting many neonates. Bilirubin is a reddish yellow crystalline pigment $C_{33}H_{36}N_4O_6$ occurring in bile, blood, urine, and gallstones sometimes in combination with protein and formed by reduction of biliverdin. Bilirubin is produced when red blood cells get old and are broken down by the body. Normally it is processed in the liver and then deposited in the intestine so it can come out in the stool. Bilirubinemia is a condition characterized by elevated bilirubin levels in the bloodstream. The red blood cells of babies have shorter lives than adult red blood cells; bruising at birth may cause a larger number of red cells to be broken down. All of the bilirubin from these cells needs to be processed by the baby's liver. Premature babies do not have fully developed organs. Their livers cannot process bilirubin rapidly. Their intestines may not move much in the first few days especially if they are sick and not being fed. Extremely high levels of bilirubin can be harmful, causing brain damage.

[0005] Several tests may be utilized to detect the presence of bilirubinemia or hyperbilirubinemia. These include auditory screening tests, where an detected hearing loss is predictive of bilirubin, a breath gas analysis, where end-tidal carbon-monoxide levels are predictive of bilirubin, and a blood analysis to detect the levels of bilirubin and related blood chemistry components.

[0006] For example, the measuring or monitoring of evoked or continuous bioelectric signals in a patient, such as an infant or other human patient who may be incapable of audiometric behavioral responses, is becoming an increasingly common method for initial patient screening or monitoring, and is used in auditory testing programs to identify hearing abnormalities, or in anesthesia and sedation monitoring to determine a patient's state, such as an awareness level.

[0007] In auditory screening, the functionality of the outer hair cells of the inner ear can be assessed with measurements of sounds in the external ear canal generated by the inner ear, called otoacoustic emissions (OAE), in response to clicks, called transient evoked OAE (TEOAE), or to two tones, called distortion product OAE (DPOAE).

[0008] A TEOAE is generated in response to a transient test signal, usually a sequence of square waves (click). The level of these clicks is typically between 35 dB SPL and 90 dB SPL. In response to these test signals, a normal human ear generates a wide band signal up to 20 ms in duration after each click. The spectrum S_T of this response can be compared against the spectrum of ambient noise S_A to identify normal or abnormal hearing.

[0009] Similarly, a DPOAE is generated in response to the presentation of two simultaneous tonal signals, s_1 and s_2 with associated frequencies f_1, and f_2, with $f_2 > f_2$.

Typically, the ratio of the frequency of f_2 to f_1 is selected to be about 1.2, with amplitudes $|s_1|$= 65 dB SPL and $|s_2|$= 55 db SPL in the ear canal. In response to these signals, a normal human ear generates, among others, a third tonal signal, the DPOAE at frequency 2f1-f2, which can be measured to identify normal or abnormal hearing

[0010] Surface electrodes are utilized to detect bioelectric signals in a patient which are generated in response to an auditory stimulus. These bioelectric signals can be used both in auditory screening and in brain activity monitoring during anesthesia or sedation. An auditory evoked potential (AEP) is produced upon presentation of an auditory stimulus or series of stimuli, such as clicks or tone bursts. The AEP can be characterized by three components which refer to the latency of the response with respect to the stimulus; these are referred to as early, middle, and late components.

[0011] The early or short latency component of the AEP, the auditory brainstem response (ABR), occurs within the first 15ms after the presentation of the auditory stimulus and is widely used for clinical evaluation of hearing in infants and other individuals who are unable to effectively communicate whether a sound was detected. In individuals with normal hearing, the ABR generates a characteristic neural waveform. Auditory testing using the ABR typically involves a visual or statistical comparison of a tested individual's waveform to a normal template waveform. Like other evoked potentials, the ABR is recorded from surface electrodes on the scalp. However, the electrodes also record the background noise comprised of unwanted bio-potentials resulting from other neural activity, muscle activity, and unwanted non-physiological sources in the environment.

[0012] The middle component of the AEP, the auditory mid-latency response (AMLR), also referred to as the middle latency auditory evoked potential (MLAEP) occurs 15ms – 100ms after the presentation of the auditory stimulus, and is believed to reflect primary, non-cognitive, cortical processing of auditory stimuli. Lately, the AMLR, or MLAEP, has been of particular interest as a measure of depth of anesthesia, as it is known that the AMLR consists of positive and negative waves that are sensitive to sedatives and anesthetics. In general, increasing the level of sedation or anesthetic increases the latency of these waves, and simultaneously decreases the amplitudes. For monitoring purposes, changes in the AMLR waves are quantified as latency to peak, amplitude, and rate of change, and are sometimes combined in a single index.

[0013] The final component of the AEP, the auditory late response (ALR) occurs about 100ms after the auditory stimulus, and is believed to be especially sensitive to the level of sedation or anesthesia applied to a patient, and exhibits a distinct flattening of the waveform at a relatively light level of sedation or anesthesia, among other features.

[0014] It is further known that a 40Hz auditory signal introduced to a patient's ear can induce an enhanced "steady-state" AEP signal (SSEP) in the patient's nervous system. Conventional signal averaging over a period of time is required to extract this "steady-state" AEP signal from background EEG signals, and adequate responses usually may be obtainable in about 30-40 seconds. The existence of an intact AEP is believed to be a highly specific indicator for the awake state of a patient, and gradual changes in the depth of sedation or anesthesia appear to be reflected by corresponding gradual changes in the AEP.

[0015] As with auditory screening procedures, a breath gas analysis can provide a doctor with useful information about a patient's condition and can measure end-tidal carbon-monoxide levels which are predictive of bilirubin. Measurements of the proportions and levels of gases present in a patient's breath are represented by periodic or time-varying gas patterns. Analysis of the gases present in the breath of a patient is commonly utilized as a non-invasive procedure for obtaining a representation of the proportions and levels of gases in the patient's blood. It is known that air in the deep alveolar pockets of a patient's lungs is composed of a mixture of gases which is in close equilibrium with the mixture of gases present in the patient's blood. Accordingly, during a patient's breath cycle, the last portion of an exhalation, i.e. the "end-tidal" portion is believed to provide the most accurate representation of the mixture of gases in the deep alveolar pockets of the lungs, and must be identified and captured for gas analysis.

[0016] Finally, blood analysis is a well known procedure for identifying information about the blood chemistry of a patient. Blood analysis may be invasive, wherein a sample of the patient's blood is extracted and analyzed directly, using either chemical reactions or spectroscopic analysis. Alternatively, blood analysis may be non-invasive, wherein spectroscopic analysis is conducted of the patient's blood in-situ, typically by optical spectroscopy of a thin portion of the patient's skin, i.e. the webs of the fingers or finger tips, where light from a light source can pass through the skin and be detected.

[0017] It is known that a positive result from two or more different testing methods provides a more accurate test for bilirubinemia or hyperbilirubinemia. Accordingly, it would be highly advantageous to provide a portable, easy to use, medical testing

device which is capable of performing a variety of tests, the results of which may be utilized to predict bilirubinemia or hyperbilirubinemia in a human infant, as well as detect other abnormal conditions which are routinely tested for during infant screening.

BRIEF SUMMARY OF THE INVENTION

[0018] Briefly stated, the present invention is a portable medical screening device configured to measure and monitor combinations of blood chemistry, breath gasses, and bioelectrical signals such as evoked auditory signals, EEG signals, and EKG signals associated with human auditory testing to facilitate detection of abnormal medical conditions or disorders in human patients, particularly in infants. The medical screening device includes a portable hand-held enclosure containing a digital signal processor. The processor has a computer program associated with it, capable of conducting multiple testing procedures for a test subject. A display device is coupled to the enclosure, and displays patient information, test setup procedures, and test results. The enclosure includes a plurality of I/O connection points for various test components linked to the signal processor, and an on-board power supply.

[0019] In a first embodiment, a portable medical monitoring system of the present invention is configured for the detection of one or more disorders, such as hemolysis, in a human patient. The medical monitoring system consists of an auditory response testing subsystem configured to measure one or more responses representative of a first indicator of one or more disorders, such as a hemolysis condition, and one or more non-auditory response testing subsystems. Each of the non-auditory response testing subsystems is configured to measure one or more additional characteristics of the human patient which are representative of the one or more disorders, such as the

hemolysis condition. A signal processor is operatively coupled to each of said testing subsystems, and includes a computer program operated on command by a user to selectively operate each of said testing subsystems and to generate a cumulative index representative of the one or more disorders, responsive to the detected presence of indicators of the one or more disorders.

[0020] In an alternate embodiment of the present invention, a medical monitoring system for the detection of one or more disorders in a human patient consists of a portable hand-held enclosure within which are disposed a plurality of testing subsystems. Each testing subsystems is configured to measure one or more discrete characteristics of the human patient which are representative of a the one or more disorders. Connection points are provided on the enclosure for operatively coupling one or more test instruments to the plurality of testing subsystems, and a self-contained power supply is disposed within the enclosure for operating said plurality of testing systems. Preferably, the testing subsystems include at least an auditory screening subsystem, a breath gas analyzer subsystem, and a blood analysis subsystem.

[0021] The foregoing and other objects, features, and advantages of the invention as well as presently preferred embodiments thereof will become more apparent from the reading of the following description in connection with the accompanying drawings.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0022] In the accompanying drawings which form part of the specification:

[0023] Figure 1 is a top plan view of one illustrative embodiment of an electrical testing device of the present invention;

[0024] Figure 2 is a view in end elevation of the electrical testing device;

[0025] Figure 3 is a view in end elevation of the electrical testing device end opposite to that shown in Fig. 2;

[0026] Figure 4 is a system block diagram representation of the components of the medical screening device of the present invention; and

[0027] Figure 5 is a software block diagram representing the software components of the medical screening device of the present invention.

[0028] Corresponding reference numerals indicate corresponding parts throughout the several figures of the drawings.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0029] The following detailed description illustrates the invention by way of example and not by way of limitation. The description clearly enables one skilled in the art to make and use the invention, describes several embodiments, adaptations, variations, alternatives, and uses of the invention, including what is presently believed to be the best mode of carrying out the invention.

[0030] Referring now to Figure through Figure 3, reference numeral 100 illustrates one embodiment of the medical screening device of the present invention. The screening device 100 includes an enclosure 102 which can be carried by the user without compromise, and represents a portable hand-held device having full functionality described below. The screening device 100 includes a keyboard 104, which is preferably a membrane switch keyboard incorporating only the minimum keys necessary for operation of the device 100. All keys are programmable, except for the on/off key 105. A display 106 and one or more function indicator light emitting diodes (LEDs) 108 are also included in the enclosure 102, as well as a set of interfaces 110A –

110E for a plurality of testing probes, electrodes, gas analyzers, optical probes, or signal output components 112. In the embodiment illustrated, the enclosure 102 further houses an infrared port 114, and an RS-232 port 116, an at least one probe connection 118 suitable for use with an input probe 120, such as an ear probe. A power coupling 122 is provided for connecting the screening device 100 to an external power source, permitting recharging of an internal power source when not in use.

[0031] Turning to Figure 2, a microprocessor 200 is the control for the screening device 100. The microprocessor 200 may be any of a variety of micro controller or microprocessor circuits, such as a general purpose logic circuit, or a specialized digital signal processor, provided that the microprocessor 200 is capable of implementing the necessary software instructions to carry out the function of the screening device 100.

[0032] In the preferred embodiment illustrated, all signal processing and data acquisition functions described herein are performed or controlled by the microprocessor 200. The microprocessor 200 is further configured to control all input and output functions of the screening device 100, such as graphic or display functions, a user interface 202, a computer host interface 204, patient data storage functions, and other device functionality.

[0033] A memory or data storage subsystem 206 is connected to the microprocessor 200. The memory subsystem 206 includes a random access memory (RAM) 208 for storing intermediate results and holding temporary data, and a flash memory (EEPROM or EPROM) 210 for storing non-volatile, electrically programmable variable, patient data, and configuration information.

[0034] Signals for data acquisition and control of external components are conveyed between the microprocessor 200 and one or more dedicated subsystems or sensor via the data acquisition / data synthesis bus 212. In the embodiment shown in Figure 4, a breath gas analyzer subsystem 300, a optical blood gas monitor system 400, a bioelectric signal measurement subsystem 500, and an auditory testing subsystem 600 are each operatively coupled to exchange data and instructions through the data acquisition / synthesis bus 212. Those of ordinary skill in the art will recognize that a variety of additional subsystems or modules 700, each configured to receive data from one or more associated sensors 702 may be operatively coupled to the data acquisition / synthesis bus 212.

[0035] In one embodiment, the breath gas analyzer subsystem 300 consists of a conventional pneumatic system 302 configured for receiving a patient's breath gas exhalations through a cannula 304 or other suitable breath gas receiver, and for selectively providing samples of the patient's breath gas exhalations to one or more gas monitors such as a carbon monoxide (CO) monitor 306 and a capnometer 308. It is known that the concentration of carbon monoxide gas in a patient's exhaled breath is correlated with the patient's bilirubin production levels, and accordingly, can provide an indicators of an imbalance. For example, a sample of exhaled breath is analyzed to determine the amount of CO in the end-tidal portion of the breath, which can be used as an index of the rate of red blood cell decomposition (hemolysis), which in human neonates can lead to hyperbilirubinemia (jaundice). Alternatively, indicators of other disorders such as lactose malabsorption may be detected through breath gas analysis.

[0036] Other breath gas measurements may include, but are not limited to, measurements of the concentrations of oxygen, carbon dioxide, nitrous oxide, and NO_2. Measurements of breath gas concentrations acquired by the gas monitors 306 and 308 are made available to the microprocessor 200 through the data acquisition / synthesis bus 212. Correspondingly, operation of the pneumatic system 302 is regulated by the microprocessor 200 through the data acquisition / synthesis bus 212. Those of ordinary skill in the art will recognize that the pneumatic system 302 may include one or more microprocessors or logic circuits which operate independently of the microprocessor 200 of the screening device 100 in order to carry out functions associated with the pneumatic system 302 and the gas monitors 306, 308.

[0037] In one embodiment, the optical blood gas monitor system 400 consists of a conventional pulse oximeter 402 configured to receive data from an oximeter sensor 404, and a conventional cutaneous optical sensor 406 configured for spectrophotometric analysis of a patient's blood and tissues to determine the presence of, and accumulation of blood analytes, such as, but not limited to, biliruben, hemoglobin, hematocrit, glucose, and lactate. Spectrophotometry works by shining a plain or modulated light at a patient's skin and collecting the reflected light in various spectral bands. The various wavelengths of light present or absent in the reflected light corresponds to the presence and concentration of various analytes in the patient's blood and intervening tissues, permitting the identification of the relative levels of the analytes present in the patient's blood. Pulse oximetery measurements acquired by the pulse oximeter 402, and blood analytes or gas concentrations acquired by the cutaneous optical sensor 406 are made available to the microprocessor 200 through...

the data acquisition / synthesis bus 212. Those of ordinary skill in the art will recognize that either the pulse oximeter 402 or the cutaneous optical sensor 406 may include one or more microprocessors or logic circuits which operate independently of the microprocessor 200 of the screening device 100 in order to carry out functions associated sensors 402, 406.

[0038] In one embodiment, the bioelectric signal measurement subsystem 500 consists of a conventional electro-encephalogram (EEG) measurement system 502 configured to receive bioelectric signals through one or more EEG electrodes 504, and a conventional electrocardiogram (EKG) measurement system 506 configured to receive bioelectric signals through one or more EKG electrodes 508. Output signals from the EEG measurement system 502 and the EKG measurement system 506 are made available to the microprocessor 200 through the data acquisition / synthesis bus 212. It is known that EEG and EKG signals are predictive or indicative of a variety of medical conditions in a patient. Those of ordinary skill in the art will recognize that either the EEG measurement system 502 or the EKG measurement system 506 may include one or more microprocessors or logic circuits which operate independently of the microprocessor 200 of the screening device 100 in order to carry out functions associated sensors 502, 506.

[0039] In one embodiment, the auditory testing subsystem 600 consists of a conventional otoacoustic emission (OAE) amplifier 602, configured to receive acoustic signals from a microphone 604, and an audio signal amplification system 606, configured to present acoustic signals to a patient's ear through a speaker 608. The microphone 604 and speaker 608 may optionally be combined in a single ear probe

610, configured for insertion into the external ear canal of a patient. Output signals from the OAE amplifier 602 made available to the microprocessor 200 through the data acquisition / synthesis bus 212. Correspondingly, control signals to the audio signal amplification system 606 are communicated from the microprocessor 200 to the amplification system 606 through the data acquisition / synthesis bus 212. Those of ordinary skill in the art will recognize that either the OAE amplifier 602 or the audio signal amplification system 606 may include one or more microprocessors or logic circuits which operate independently of the microprocessor 200 of the screening device 100 in order to carry out functions associated the components 602, 606.

[0040] Turning to Figure 5, computer program code and operating instructions for the microprocessor 200 are shown. At the basic or physical level, a set of device drivers 800 configured to handle the necessary data communication and exchanges between the microprocessor 200 and a variety of interconnected components, such as the user interface 202, computer host interface 204, data store 206, and data acquisition / synthesis bus 212 are shown.

[0041] Next, the operating system 802 is shown above the device drivers, and implements the operating instructions and program code required to direct the device drivers for the exchange of data and control of the various interconnected components. The operating system 802 is further configured to control data acquisition and multiplexing operations 804 on the data acquisition / synthesis bus 212, and to control data retrieval and data storage in the patient database memory structures 806. The operating system 802 further provides a structure in which program modules associated individual subsystems of the screening device 100 can operate. These modules may

include a gas analysis program module 808, an optical spectral analysis module 810, a patient stimulus generator module 812, a hearing screening module 814, a bioelectric signal analysis module 816, and any other optional modules 818 associated with additional subsystems 700 in the screening device 100.

[0042] Each program module is configured to receive operator instructions and to display results to an operator through the user interface 820. Correspondingly, each program module is configured for data acquisition, either from an external sensor such as the pneumatic system 302, oximeter sensor 404, EEG or EKG electrodes 504, 508, or earprobe 610 through the data acquisition and multiplexing module 804, or from the patient database 806. Each module 808 – 818 is configured to operate independently of the other modules present in the screening device 100, and may selectively display obtained results or measurements for an operator. Each module 808-818 may be optionally be configured to utilized results obtained by one or more different modules 808-818 to generate one or more combined results, for example, to provide a numerical index representative of a specific condition or disorder in a patient based upon results from different measurements or modules.

[0043] For example, measurements obtained by the gas analysis module 808 which are associated with hemolysis may be combined with measurements obtained by the optical spectral analysis module for cutaneous measurements of biliruben accumulation levels to provide an index representative of hemolysis or a biliruben production rate and biliruben accumulation levels which is a powerful indicator of bilirubinemia. Similarly, measurements of other factors from multiple modules may be acquired which are

representative of other disorders in the human patient, for example, lactose malabsorption.

[0044] The present invention can be embodied in-part in the form of computer-implemented processes and apparatuses for practicing those processes. The present invention can also be embodied in-part in the form of computer program code containing instructions embodied in tangible media, such as floppy diskettes, CD-ROMs, hard drives, or an other computer readable storage medium, wherein, when the computer program code is loaded into, and executed by, an electronic device such as a computer, micro-processor or logic circuit, the device becomes an apparatus for practicing the invention.

[0045] The present invention can also be embodied in-part in the form of computer program code, for example, whether stored in a storage medium, loaded into and/or executed by a computer, or transmitted over some transmission medium, such as over electrical wiring or cabling, through fiber optics, or via electromagnetic radiation, wherein, when the computer program code is loaded into and executed by a computer, the computer becomes an apparatus for practicing the invention. When implemented in a general-purpose microprocessor, the computer program code segments configure the microprocessor to create specific logic circuits.

[0046] In view of the above, it will be seen that the several objects of the invention are achieved and other advantageous results are obtained. As various changes could be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

CLAIMS:

1. An medical monitoring system for the detection of one or more disorders in a human patient, comprising:

an auditory response testing subsystem, said auditory response testing subsystem configured to measure one or more responses of the human patient to an auditory stimulus, said responses representative of a first indicator of the one or more disorders;

one or more non-auditory response testing subsystems, said one or more non-auditory response testing subsystems configured to measure one or more characteristics of the human patient, said one or more characteristics representative of one or more additional indicators of the one or more disorders; and

a microprocessor operatively coupled to each of said testing subsystems, said signal processor having a computer program operated on command by a user, said program configured to selectively operate each of said testing subsystems and to generate a cumulative index representative of the one or more disorders responsive to two or more indicators of the one or more disorders.

2. The medical monitoring system of Claim 1 wherein said one or more non-auditory response testing subsystems includes a breath gas monitoring subsystem.

3. The medical monitoring system of Claim 2 wherein said breath gas monitoring subsystem is configured to measure at least a concentration of carbon monoxide exhalations from the human patient, said carbon monoxide concentration an indicator of a hemolysis condition.

4. The medical monitoring system of Claim 1 wherein said one or more non-auditory response testing subsystems includes a blood analysis subsystem.

5. The medical monitoring system of Claim 4 wherein said blood analysis subsystem is configured to measure at least a presence or absence of one or more chemical compounds indicative of a hemolysis condition.

6. The medical monitoring system of Claim 4 wherein said blood analysis subsystem is further configured for non-invasive optical blood analysis.

7. The medical monitoring system of Claim 1 further including a portable hand-held enclosure, said signal processor, said auditory response testing subsystem, and said one or more non-auditory response testing subsystems disposed within said enclosure;

one or more connection points on said enclosure for operatively coupling one or more instruments to said auditory response testing subsystem and said one or more non-auditory response testing subsystems; and

a power supply for operating each of said testing subsystems.

8. The medical monitoring system of Claim 7 wherein said one or more instruments are selected from a set of instruments including microphones, acoustic emitters, electrodes, gas analyzers, and optical sensors.

9. The medical monitoring system of Claim 1 wherein said one or more non-auditory response testing subsystems includes a bioelectric signal measurement subsystem, said bioelectric signal measurement subsystem configured to measure at least a an EKG signal from a patient.

10. The medical monitoring system of Claim 9 wherein said microprocessor is further configured to evaluate said EKG signal to detect one or more predetermined anomalies representative of a disorder in a patient.

11. The medical monitoring system of Claim 1 wherein said microprocessor is further configured to selectively display results from a single testing subsystem.

12. An medical monitoring system for the detection of one or more disorders in a human patient, comprising:

a portable hand-held enclosure;

a plurality of testing subsystems disposed within said enclosure, each of said plurality of testing subsystems configured to measure one or more discrete characteristics of the human patient, said one or more discrete characteristics representative of the one or more disorders;

one or more connection points on said enclosure for operatively coupling one or more instruments to said plurality of testing subsystems; and

a power supply for operating said plurality of testing systems.

13. The medical monitoring system of Claim 12 wherein said plurality of testing subsystems are selected from a set of testing subsystems including an auditory screening subsystem; a breath gas analyzer subsystem; a blood analysis subsystem; and a bioelectric signal measurement subsystem.

14. The medical monitoring system of Claim 13 wherein said blood analysis subsystem is a non-invasive optical blood analysis subsystem.

15. The medical monitoring system of Claim 12 wherein said one or more instruments are selected from a set of instruments including microphones, acoustic emitters, electrodes, gas collectors, and optical sensors.

16. The medical monitoring system of Claim 12 further including a microprocessor housed within said enclosure, said microprocessor having a computer program operated on command by a user, said program configured to selectively operate said plurality of testing subsystems, and to provide results to said user.

17. The medical monitoring system of Claim 16 further including a display device mounted to said enclosure, said display device operatively connected to said microprocessor.

18. The medical monitoring system of Claim 16 wherein said program is configured to utilize results from at least two of said testing subsystems to generate an cumulative index value representative of the one or more disorders.

19. The medical monitoring system of Claim 12 wherein the one or more disorders include at least one disorder from a set including hemolysis, lactose malabsorption, and hyperbilirubinemia.

20. A self-contained, portable medical monitoring system for the detection of one or more disorders in a human patient, comprising:

a plurality of detection means for acquiring two or more different measurements of patient characteristics representative of the one or more disorders; and

a processor means coupled to said plurality of detection means, said processor means configured for evaluating said two or more different measurements and for

generating a index based on said two or more different measurements representative of the presence of the one or more disorders.

21. The self-contained, portable medical monitoring system of Claim 18 wherein said processor is further configured to display at least one of said two or more different measurements individually.

ABSTRACT OF THE DISCLOSURE

A medical screening device configured to measure and monitor combinations of blood chemistry, breath gasses, and bioelectrical signals such as evoked auditory signals and EEG signals associated with human auditory testing to facilitate detection of abnormal medical conditions or disorders in human patients by providing a index representative of one or more detected disorders.

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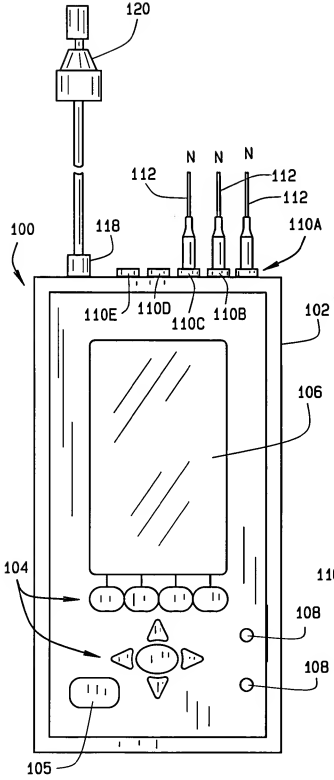

FIG. 1

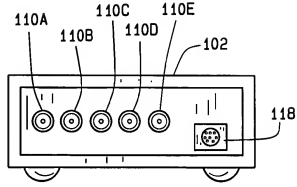

FIG. 2

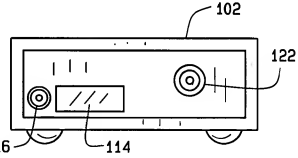

FIG. 3

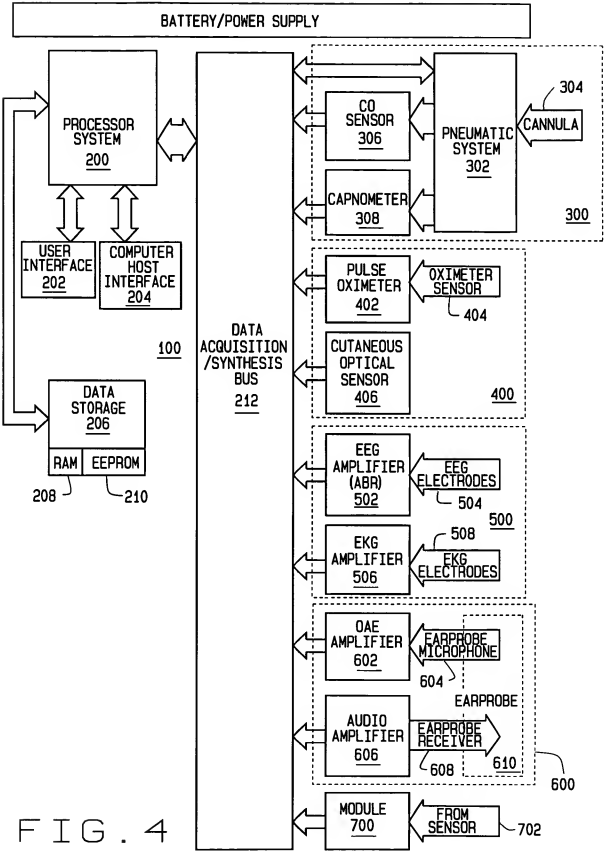
BATTERY/POWER SUPPLY
PROCESSOR SYSTEM 200
USER INTERFACE 202
COMPUTER HOST INTERFACE 204
DATA STORAGE 206
RAM
EEPROM
208
210
100
DATA ACQUISITION /SYNTHESIS BUS 212
CO SENSOR 306
CAPNOMETER 308
PNEUMATIC SYSTEM 302
304
CANNULA
300
PULSE OXIMETER 402
OXIMETER SENSOR
404
CUTANEOUS OPTICAL SENSOR 406
400
EEG AMPLIFIER (ABR) 502
EEG ELECTRODES
504
500
EKG AMPLIFIER 506
508
EKG ELECTRODES
OAE AMPLIFIER 602
EARPROBE MICROPHONE
604
EARPROBE
AUDIO AMPLIFIER 606
EARPROBE RECEIVER
608
610
600
MODULE 700
FROM SENSOR
702

FIG. 4

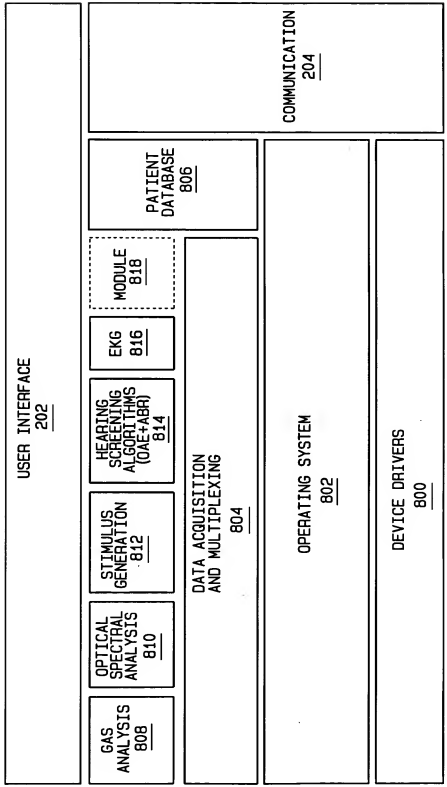
USER INTERFACE
202
GAS ANALYSIS
808
OPTICAL SPECTRAL ANALYSIS
810
STIMULUS GENERATION
812
HEARING SCREENING ALGORITHMS (OAE+ABR)
814
EKG
816
MODULE
818
DATA ACQUISITION AND MULTIPLEXING
804
PATIENT DATABASE
806
COMMUNICATION
204
OPERATING SYSTEM
802
DEVICE DRIVERS
800

FIG. 5